IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No:	10/774,021
Applicant(s):	Orn Adalsteinsson
Filed:	February 6, 2004
Title:	GLUCOSAMINE AND EGG FOR REDUCING INFLAMMATION
TC/A.U.:	1648
Examiner:	Stacy Chen Brown
Confirmation No.:	Unknown
Docket No.:	ARK-153US1

DECLARATION OF MR. LESLIE A. CONFER UNDER RULE 132

Mail Stop
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Mr. Leslie A. Confer, hereby declare that:

1. I am Manager of Quality and Technical Services at Arkion Life Sciences LLC.

2. I have earned a Bachelor's degree in Biochemistry from the Pennsylvania State University. My experience has spanned more than 20 years and has included work in biology, immunology, microbiology, and biochemistry, including research positions at well known academic institutions (Johns Hopkins School of Medicine) and FDA or USDA licensed medical diagnostics manufacturers.

3. From my experience in the fields of biology, immunology, microbiology, and biochemistry, I am knowledgeable about microbiology, immunological processes and the development of products that affect the immune system.

4. The following bacterial names, set forth in the Table 1 PL-100 Bacterial List of the above patent application, were listed in error:

Salmonella simulans
Salmonella dysenteriae
Salmonella epidermidis
Pseudomonas vulgaris

5. It is obvious that these four bacterial names originally listed do not exist, and, as such, clearly resulted from a transcriptional error.

6. Accepting the authority of "The List of Bacterial Names with Standing in Nomenclature" (http://www.bacteria.net) copyright 1997-2003 J.P. Euzeby., a search by species reveals the following alternatives:

Corynebacterium simulans
Staphylococcus simulans

Brachyspira hyodysentariae
Serpula hyodysentariae
Serpulina hyodysentariae
Treponema hyodysentariae
Shigella dysenteriae

Brevibacterium epidermidis
Staphylococcus epidermidis

Cellvibrio vulgaris
Desulfovibrio vulgaris
Nitrobacter vulgaris
Proteus vulgaris
Tectibacter vulgaris
Thermoactinomyces vulgaris
Streptomyces thermovulgaris

7. The following four bacterial names are being submitted as the correct names to replace those erroneously listed:

Staphylococcus simulans
Shigella dysentariae
Staphylococcus epidermidis
Proteus vulgaris

8. The four proposed replacement bacterial names are valid bacterial names in nomenclature.

9. In determining proper replacement bacterial names for those erroneously listed, one is compelled to restrict the choices of genus and species names to those that are consistent with the PL-100 bacterial listing. Such restriction leads to the conclusion that the obvious genus and species replacements that are consistent with the PL-100 listing, and valid in the nomenclature, are those being offered as correct. For example, in the case of the *vulgaris* species, the only genus alternatives, other than that being offered as correct (i.e. *Proteus*), are environmental organisms that are non-pathogenic to humans or animals. Consideration of these genuses would be inconsistent with the other bacterial antigens set forth in the PL-100 bacterial listing which are all pathogenic to humans and/or animals.

10. Therefore, in my opinion, the incorporation of the erroneously listed bacteria names resulted from mere transcriptional errors, and the bacterial genus and species being offered as corrections are the only true and valid genus and species replacements that would apply.

11. In my opinion, others skilled in the art of biology, immunology, microbiology, and biochemistry, would draw the same conclusions, after studying the same materials, which are set forth above. Moreover, I know of no other data, which would alter my conclusions.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the above-identified application or any patent issued thereon.

Dated: 03/23/2004

Leslie A. Confer

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DECLARATION OF DR. SUBRAMANIAN IYER UNDER RULE 132

Mail Stop
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P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Dr. Subramanian Iyer, hereby declare that:

1. I am Director of Research & Development at Arkion Life Sciences, the inventor of the claimed invention of the patent application identified above.

2. I have earned a Bachelor's degree in Microbiology, a Master's degree in Biochemistry (Human Nutrition), and a Doctoral degree in Immunology. My postdoctoral research has spanned more than 15 years and has included work in genomics and protein molecular biology.

3. From my experience in the fields of molecular biology and immunology, I am very knowledgeable about immunological processes and the development of products that affect the immune system.

4. The figure attached as Exhibit A depicts the effect of whole egg, egg yolk and a highly purified fraction of egg (3K Dalton permeate) in the Rat Type II collagen induced arthritis model. The three samples were all obtained from the same hyperimmune egg, that are produced by immunizing chickens with the PL-100 vaccine referred to in Example 1 of the application.

5. The Rat Type II collagen induced Arthritis model looks at the effect of compounds on reducing the inflammation in the joints of animals that have a Rheumatic Arthritis like condition. Generally, in the Rat Type II collagen induced Arthritis assay, the arthritis inflammation begins around day 13 of the study.

6. As the figure depicts, the whole egg, egg yolk and 3K Dalton permeate fraction each begins to inhibit inflammation starting from day 13, whereas the control sample (saline) does not show any inhibition as the inflammation increases beginning day 13. Clearly, this data shows that the reduction of inflammation in the Type II collagen Rat model caused by the PL-100 whole egg, egg yolk and 3K Dalton Permeate is equivalent among the three samples.

7. It is hence my position that the synergistic effect observed with glucosamine and whole egg would also be expected between glucosamine and either the egg yolk from a hyperimmune egg or the active 3K Dalton fraction of a hyperimmune egg.

8. In view of this data, it is my opinion that it would be expected that any active fraction from a hyperimmune egg (i.e. any fraction that produces an anti-inflammatory effect), when combined with glucosamine, will result in an anti-inflammatory effect that is synergistically increased.

9. In my opinion, others skilled in the art of immunology and anti-inflammatory processes would draw the same conclusions, after studying the same materials, which are set forth above. Moreover, I know of no other data, which would alter my conclusions.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the above-identified application or any patent issued thereon.

Dated: 3/20/04

Subramanian

Dr. Subramanian Iyer

EXHIBIT A

Effect of Hyperimmune Egg and its Fractions on the Severity of Arthritis in the Rat Type II Collagen Model